

Objective

Biosecurity practices, or measures to prevent the theft or sabotage of biological research materials, must coexist with biosafety. Many biosafety components, such as limiting access to dangerous pathogens, are part of a comprehensive biosecurity plan. However, potential conflicts between the two programs, such as emergency egress, may exist. Understanding the interaction between biosafety and biosecurity will help guide recommendations for facility upgrades and procedural changes, especially if facilities have limited resources to spend on these programs.

3 Main Goals of the Survey

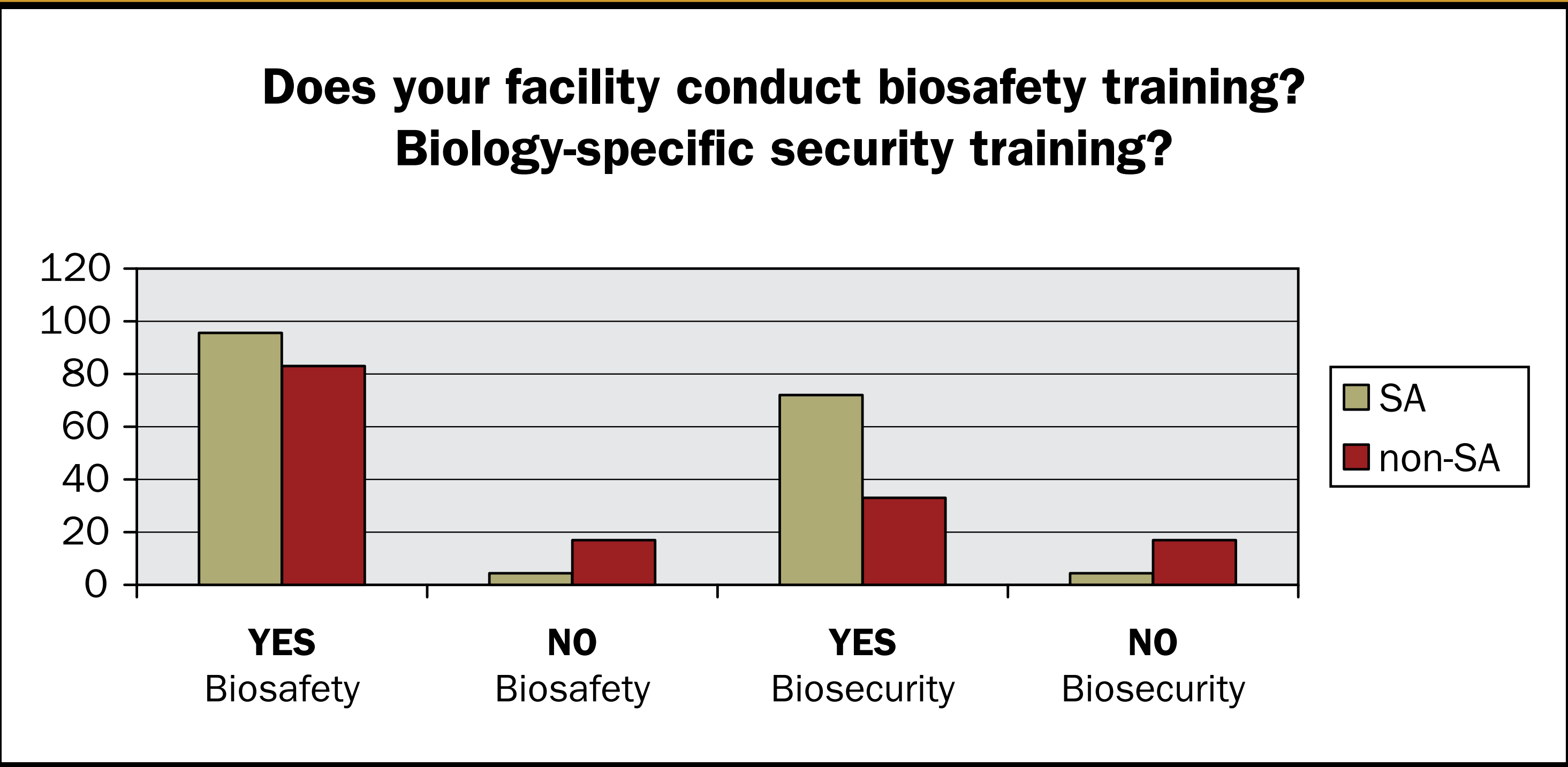
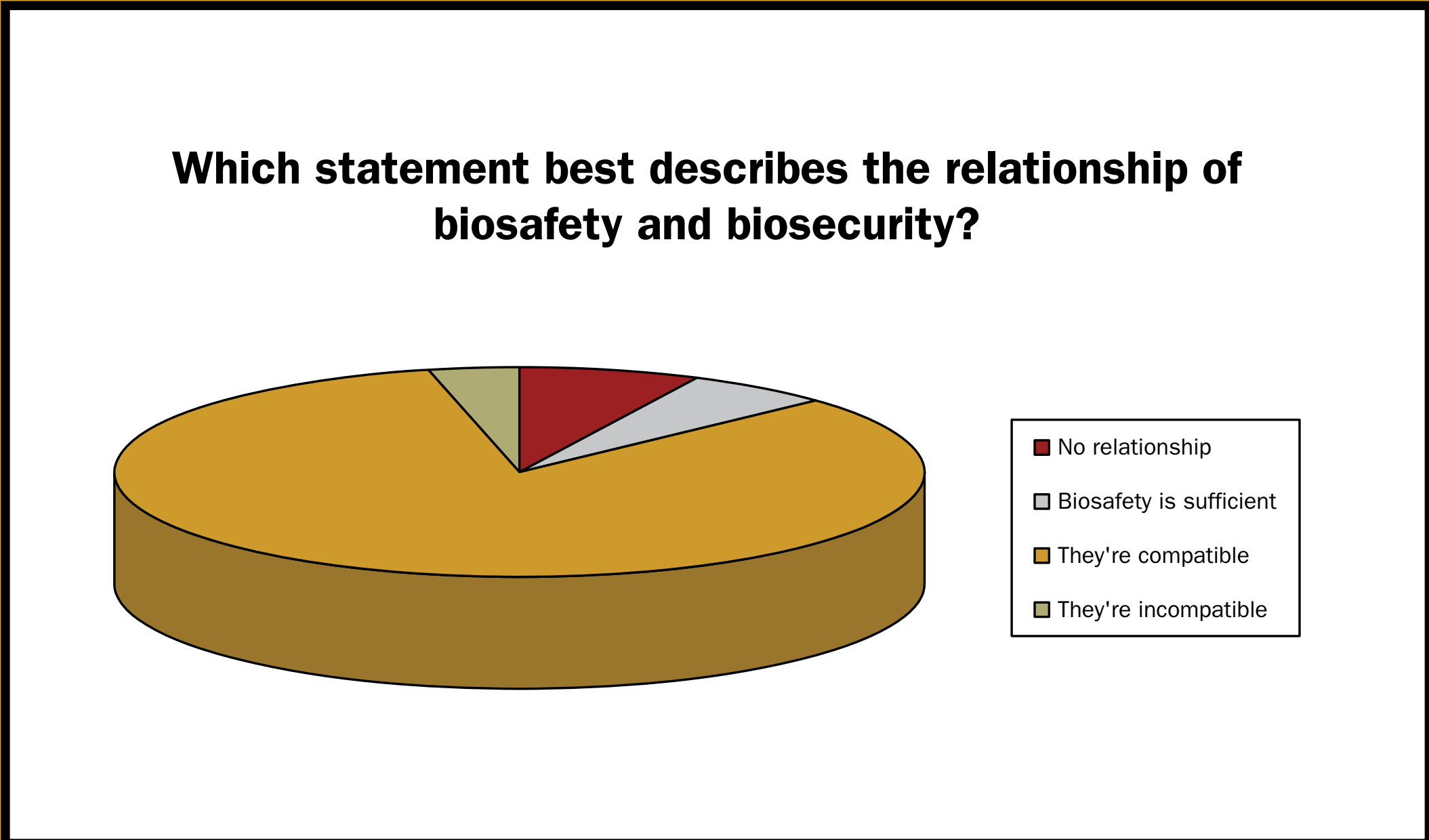
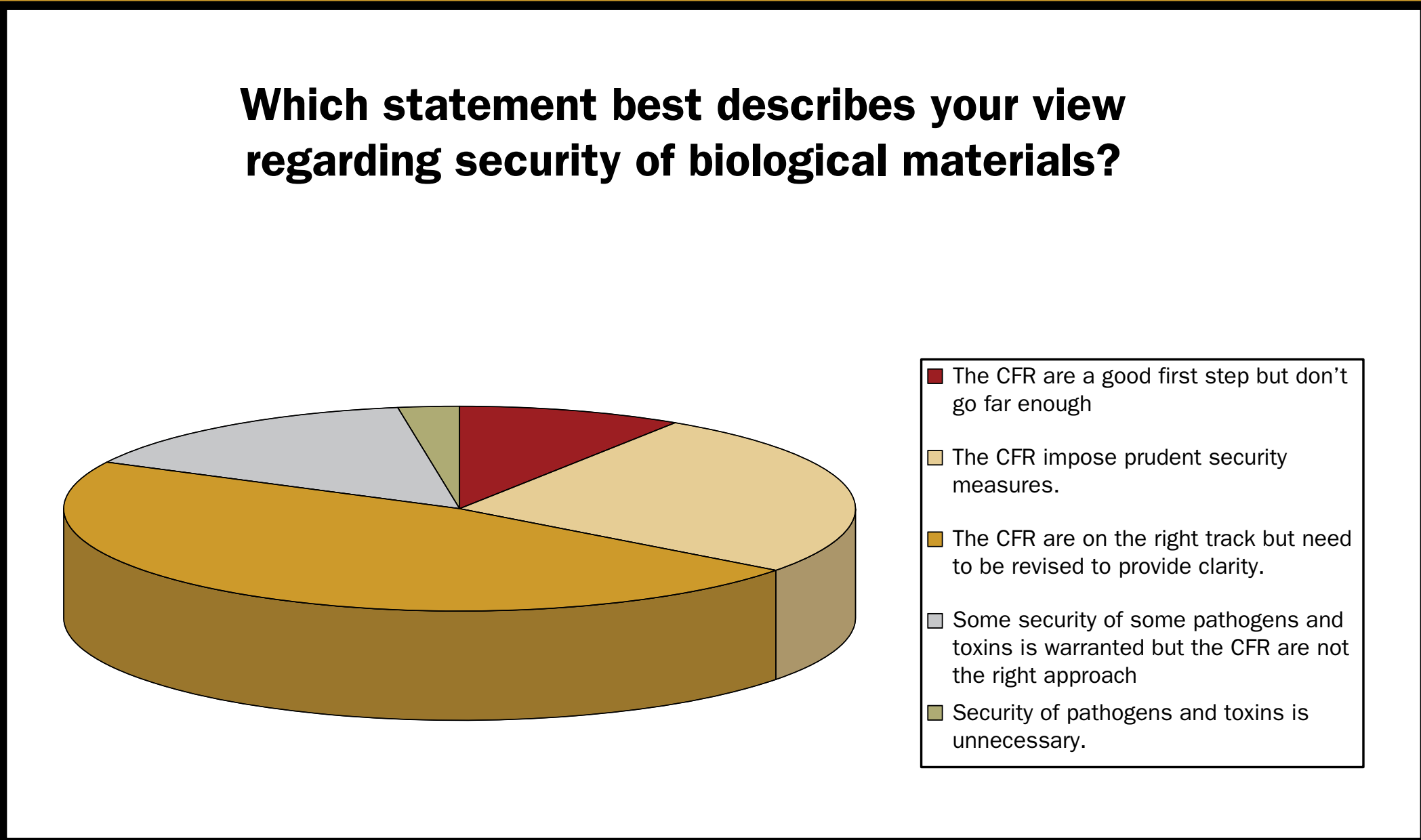
- 1) to understand the real and perceived positive and negative impacts of the interim United States Code of Federal Regulations (CFR) on those facilities that work with select agents (SA respondents)
- 2) to understand how those facilities have implemented the required biosecurity
- 3) to learn what types of biosecurity measures, if any, are in place at facilities that work with pathogens and toxins that are not select agents (non-SA respondents)

Method

Sandia National Laboratories (SNL) worked with Reed Research Group to write and conduct a survey of the United States bioscience community. Preliminary results from approximately 200 respondents were presented at the national American Biological Safety Association (ABSA) meeting in 2004. Of the respondents, only 6% identified themselves as part of the biosafety community. ABSA generously offered to sponsor a link to SNL’s survey on the ABSA website to help SNL address this gross under representation. SNL now has over 360 respondents and a balanced distribution of relevant parties.

Results

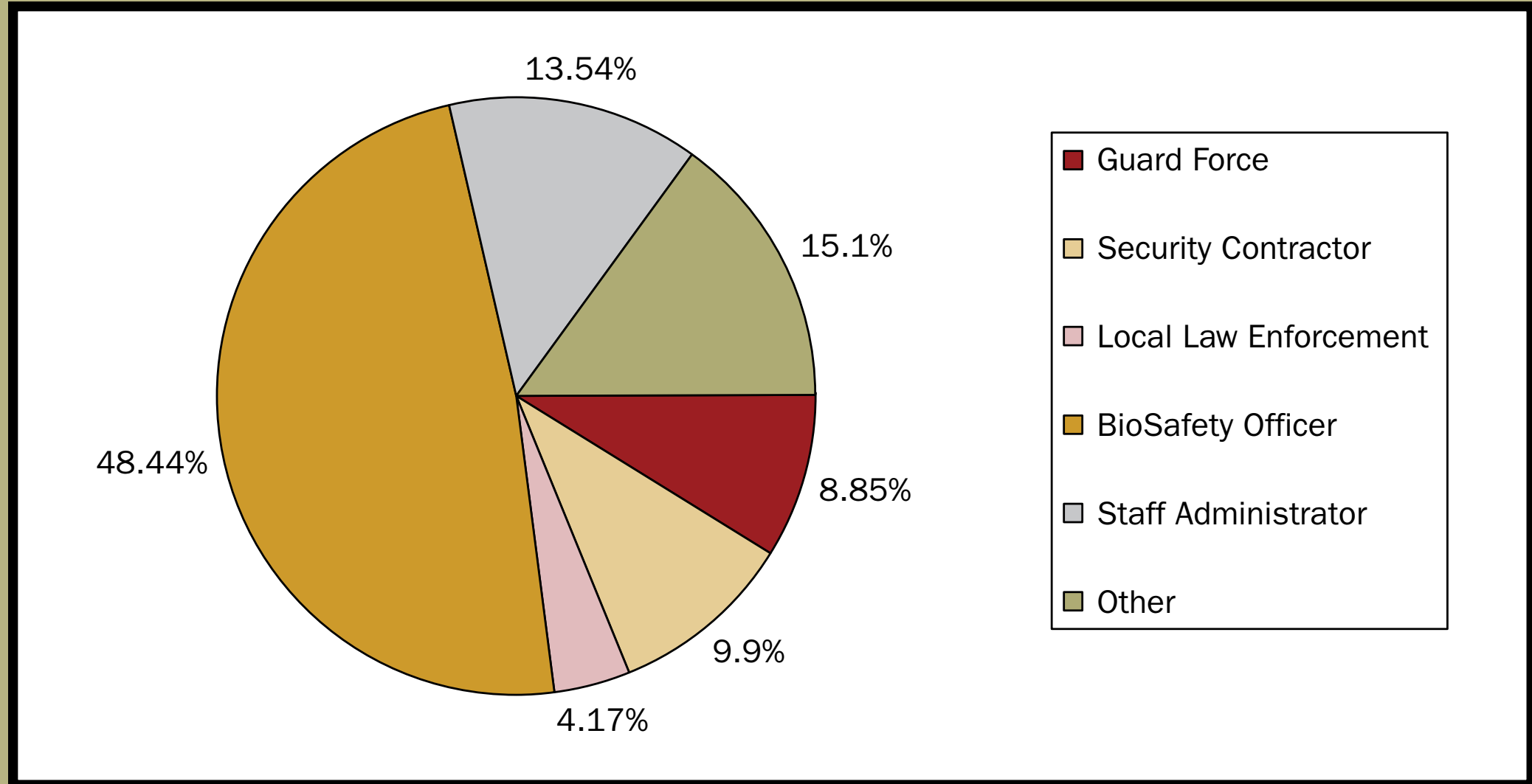
			180 SA Respondents	171 non-SA Respondents
ROLE	%	INSTITUTION	%	%
BioSafety Officers	23.6%	University	48.9%	37.4%
Responsible Official	9.4%	Clinical/Diagnostic Facilities	8.3%	24.6
Principal Investigator	16%			
Laboratory Support Staff (Technician)	12.3%	Industry	13.9%	23.4%
Director / Manager	27.6%	Government	22.2%	7.6%
Other	11%	Other	6.7%	7%



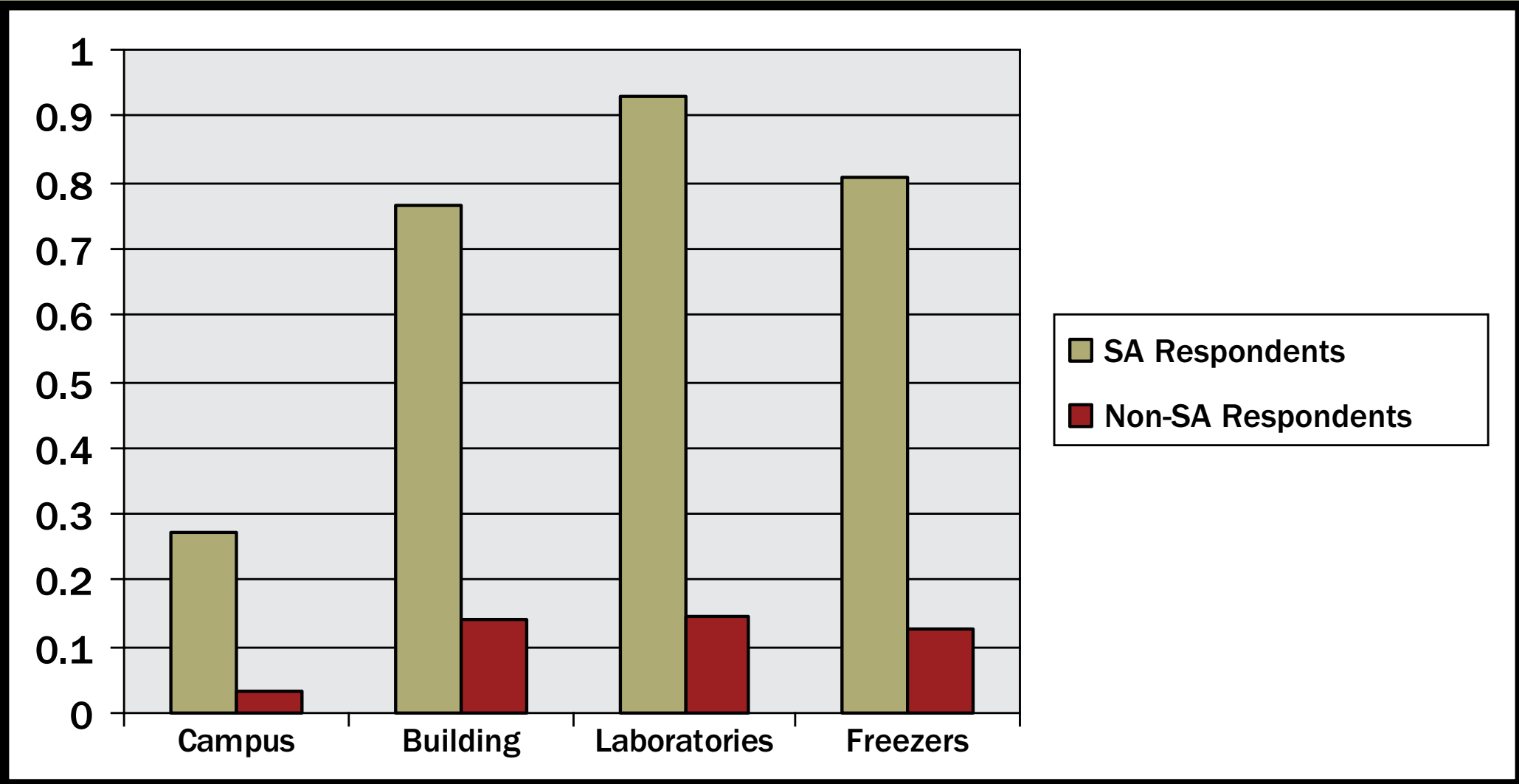
Positive Impacts	%	Negative Impacts	%
Increased awareness of risks posed by some pathogens and toxins	79	Inconvenience of increased security	45
Increased funding from the institution for needed security	31	Required to use research funding for required security upgrades	38
Increased funding for biosafety and biosecurity staff	27	Time required for staff to comply with regulations	63
Increased research funding	25	Decreased research funding	10
Increased number of researchers	10	Decrease in number of qualified researchers	14
No positive impacts	8	No negative impacts	5

Cost

Select Agent respondents were asked to provide an estimate of their facility’s overall cost of security upgrades required by the CFR. Many indicated that they were unable to estimate the cost of compliance. Of those who provided an estimate, costs ranged from \$5,000 to \$10,000,000.



Who conducted the Security Risk Assessment required by the CFR (SA Respondents)?



Areas of Controlled Access for SA and Non-SA Respondents

Non-SA respondents who had previously worked with select agents were asked:
When did you cease such work?
Before CFR regulation (Feb 2003).....50%
After CFR regulation (Feb 2003)50%

Reasons for discontinuing work with select agents were varied:
Some indicated that they were working with exempt quantities of toxins while others indicated that they ceased work because of the regulations. One respondent stated that they were unable to upgrade their facility in time to meet the CFR deadlines; another researcher had a grant revoked because they delays in receiving their select agent registration; another stated that they relocated their select agent work outside of the US.

Conclusions

Over 70% of all respondents believe that biosafety and biosecurity are compatible, while only 3% believe the two programs are incompatible. One of the goals of the survey is to probe the effect that the security measures outlined in the CFR have had on the United States bioscience community. When asked to identify the largest impact on their programs, over 70% of Select Agent respondents reported that the greatest positive impact is the increased awareness of the risks posed by some pathogens and toxins. However, the time and effort required by staff to comply with the regulations, which 52% think need to be revised to provide clarity, coupled with the inconvenience of increased security were cited as large negative impacts. Comments provided by respondents provide further insight into the relationship of biosafety and biosecurity and the results of biosecurity implementation in the United States. The results of the survey provide a foundation for discussing the prospects of successful implementation of biosecurity measures, both domestically and internationally.